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Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Rema AUTHO NECES	ORIZATION TO CHARGE T	After Allowance Communication to a Technology Center (TC) Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Proprietary Information
Firm Karen DeBenedictis or Individual Signature Date CERTIFIC I hereby certify that this correspondence is being facsimile tra first class mail in an envelope addressed to:Commissioner for Pa Typed or printed Cyathia D. Bernges	CATE OF TRANSMISSION Insmitted to the USPTO or deposited waterits, P.O.Box 1450, Alexandria, VA 22313-	I/MAILING ith the United States Postal Service/with sufficient postage as

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IN THE PAILTED STATES PATENT & TRADEMARK OFFICE

APPLICANT: Charles Price Taylor, Jr., et al. EXAMINER:

SERIAL NO. : 10/731,225 ART UNIT : 1614

FILED : December 9, 2003 PAPER NO.

FOR : Alpha2delta ligands for the treatment of fibromyalgia and other disorders

Statement as Provided by 37 CFR 1.97(b)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The Applicants submit that a Supplemental Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of the first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

As such, the Applicants respectfully requests consideration of the enclosed Supplemental Information Disclosure Statement and request that all references cited herein be printed on the face of the patent upon grant of the Application.

It is understood by the Applicants that this paper requires no fee; however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully submitted,

Dated: 6/10/04

Karen DeBenedictis Registration No. 32,977 Warner-Lambert Company 2800 Plymouth Road

Ann Arbor, MI 48105 Telephone: (734) 622-3374

Facsimile: (734) 622-1553

Confirmation No. 4925

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of

Complete if Known				
Application Number	10/731,225			
Filing Date	December 9, 2003			
First Named Inventor	Charles Price Taylor, Jr., et al.			
Art Unit	1614			
Examiner Name	Not Yet Known			
Attorney Docket Number	PC 25677A			

	U. S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
		US- US 6,359,005 B1	03/19/2002	Atul Chandra Pande					
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		^{US-} US 6,372,792, B1	04/16/2002	Guy Choulnard					
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		EP 0 974 351 A2/A3	01/26/2000	Guglietta, et al		
		WO 00/02546 A2/A3	01/20/2000	Magnus-Miller, et al		
		WO 00/31020	06/02/2000	Belliotti, et al		
		WO 00/67742 A1	11/16/2000	Magistro		
		WO 00/76958 A2/A3	12/21/2000	Belliotti, et al		
		WO 02/100347 A2/A3	12/19/2002	Gallop, et al		

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Signature	Considered

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Application Number	10/731,225				
Filing Date	December 9, 2003				
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Examiner Name	Not Yet Known				
Attorney Docket Number	PC 25677A				

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Examiner Initials*	Cite No.1	Document Number Publication D MM-DD-YY		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
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		WO 03/061656 A1	07/31/2003	Galer, et al		
		WO 98//03167 A1	01/29/1998	Singh		
		WO 98/17627 A2/A3	04/30/1998	Bryans, et al		
		WO 99/08670 A1	02/25/1999	Guglietta, et al		

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SUPPLEMENTAL				Application Number	10/731,225		
INFORMATION DISCLOSURE		Filing Date	December 9, 2003				
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(Use as many sheets as necessary)		Art Unit	1614				
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Sheet	3	of	4	Attorney Docket Number	PC 25677A		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
·	,	AMERINGEN VAN M., et al., "Drugs in Development for Social Anxiety Disorder More to Social Anxiety Than Meets the SSRI", Expert Opinion on Investigational Drugs, (2000), pp. 2215-2231, Vol. 9(10)	
		BELOZERTSEVA I V, et al., "A Pharmaco-ethological study of the GABA-ergic mechanisms regulation the depression-like behavior of mice", US National Library of Medicine, (1997), pp 1024-1031, Vol. 47	
	,	BRILEY, et al., "Fibromyalagia Syndrome", Overview of Potential Drug Targets, (2003), pp 668-673, Vol. 6	
		DANILIN V P, et al., "Effect of Fenibut on the nocturnal sleep of patients with the alcoholic abstinence syndrome", US National Library of Medicine, (1986), pp 251-254, Vol. 86(2)	
		DAVIDSON J.R.T., "Advances and Emerging Treatments in social Phobia", Journal of clinical Psychiatry, (2001), pp. 4, Vol 62(1)	
		FELTNER, et al., "A Placebo-Controlled Double-Bling Study of Pregabalin Treatment of social Phobia", European Neuropsychopharmacology, (2000), pp. S345, Vol. 10(3)	
		GUYMER E K, et al., "An Approach to Managing Fibromyalgia", Medicine Today, (2002), pp. 58-59, Vol. 3(12)	
		HIDALGO, et al., "Social Anxiety Disorder in Review", International Journal of Neuropsychopharmacology, (2001), pp 279-289, Vol. 4(3)	
		KUBOTA, et al, "Pregabalin Enhances Nonrapid Eye Movement Sleep", The Journal of Pharmacology and Experimental Therapeutics, (2001), pp 1095-1105, Vol. 299	
		MARSHALL, et al., "Changes in immune cell counts and interleukin (IL) -1 'beta' production in humans after a somnogenically active growth hormone-releasing homone(GHRH) administration", Elsevier Science Publishers, (2001), pp 227-234, Vol. 15(3)	

Examiner	Date	
Signature	Considered	

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Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known			
				Application Number	10/731,225		
				Filing Date	December 9, 2003 Charles Price Taylor, Jr., et al.		
				First Named Inventor			
				Art Unit	1614		
				Examiner Name	Not Yet Known		
Sheet	4	of	4	Attorney Docket Number	PC 25677A		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		MELTZER, et al., "Pregabalin Enhances Non-Rapid Eye Movement Sleep AND EEG Slow-Wave Activity in Rats", Society for Neuroscience Abstracts, (2001), pp 2245, Vol. 27(2)	
		SELAK I., Pregabalin, Current Opinion in Investigational Drugs, (2001), pp 828-834, Vol. 2(6)	
		VLASOV N. A., "Effects of Derivatives of GABA on Sleep Disturbances in Neurosi", Bulletin of Experimental biology and Medicine, (1978), pp. 169-171, Vol. 85(2)	

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